

§ 520.309

(6) Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[41 FR 1276, Jan. 7, 1976, as amended at 42 FR 3838, Jan. 21, 1977; 62 FR 63270, Nov. 28, 1997]

§ 520.309 Carprofen.

(a) *Specifications.* Each caplet or chewable tablet contains 25, 75, or 100 milligrams of carprofen.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use in dogs*—(1) *Amount.* 1 milligram per pound of body weight twice daily. Caplets and chewable tablets are scored and dosage should be calculated and given in half-caplet or half-chewable tablet increments.

(2) *Indications for use.* For the relief of pain and inflammation associated with osteoarthritis in dogs.

(3) *Limitations.* The safe use of carprofen in pregnant dogs, dogs used for breeding purposes, or in lactating bitches has not been established. As a class, cyclo-oxygenase inhibitory non-steroidal anti-inflammatory drugs (NSAID's) may be associated with gastrointestinal and renal toxicity. Patients at greatest risk for renal toxicity are those on concomitant diuretic therapy, or those with renal, cardiovascular, and/or hepatic dysfunction. Because many NSAID's possess the potential to induce gastrointestinal ulceration, avoid or closely monitor concomitant use of carprofen with other anti-inflammatory drugs, such as corticosteroids and NSAID's. Carprofen treatment was not associated with renal toxicity or gastrointestinal ulceration in safety studies of up to 10 times the dose in dogs. Do not use in dogs with bleeding disorders (e.g., Von Willebrand's disease). Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 66581, Dec. 18, 1996, as amended at 64 FR 32181, June 16, 1999]

§ 520.310 Caramiphen ethanedisulfonate and ammonium chloride tablets.

(a) *Specifications.* Each tablet contains 10 milligrams of 5stcaramiphen

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ethanedisulfonate and 80 milligrams of ammonium chloride.¹

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* One tablet per 15 to 30 pounds of body weight every 4 to 6 hours.¹

(2) *Indications for use.* For relief of cough.¹

[43 FR 55385, Nov. 28, 1978]

§ 520.312 Carnidazole tablets.

(a) *Specifications.* Each tablet contains 10 milligrams of carnidazole.

(b) *Sponsor.* See 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Adult pigeons: 1 tablet (10 milligrams); newly weaned pigeons: ½ tablet (5 milligrams).

(2) *Indications for use.* For treating trichomoniasis (canker) in ornamental and homing pigeons.

(3) *Limitations.* Not for use in pigeons intended for human food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism or when severely ill birds do not respond to treatment.

[54 FR 32336, Aug. 7, 1989]

§ 520.314 Cefadroxil tablets.

(a) *Specifications.* 50-, 100-, and 200-milligram tablets for dogs and cats; 1 gram tablet for dogs.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) For use in dogs as follows:

(i) *Indications for use.* For the treatment of skin and soft tissue infections including cellulitis, pyoderma, dermatitis, wound infections, and abscesses due to susceptible strains of *Staphylococcus aureus*. For the treatment of genitourinary tract infections (cystitis) due to susceptible strains of *Escherichia coli*, *Proteus mirabilis*, and *Staphylococcus aureus*.

(ii) *Amount.* Ten milligrams per pound of body weight twice daily.

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(iii) *Limitations.* The drug is administered orally. For skin and soft tissue infections, treatment should be continued for a minimum of 3 days. For genitourinary tract infections, treatment should be continued for a minimum of 7 days. Continue treatment at least 48 hours after the dog has become afebrile or asymptomatic. If no response is seen after 3 days of treatment, therapy should be discontinued and the case reevaluated. Do not treat for more than 30 days. Safety for use in pregnant bitches and stud dogs has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) For use in cats as follows:

(i) *Indications for use.* For the treatment of skin and soft tissue infections including abscesses, wound infections, cellulitis, and dermatitis caused by susceptible strains of *Pasteurella multocida*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Streptococcus* spp.

(ii) *Amount.* Ten milligrams per pound of body weight once daily.

(iii) *Limitations.* The drug is administered orally. Continue treatment at least 48 hours after the cat has become afebrile or asymptomatic. If no response is seen after 3 days of treatment, therapy should be discontinued and the case reevaluated. Do not treat for more than 21 days. Safety for use in pregnant cats and breeding male cats has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 41105, Sept. 17, 1982, as amended at 49 FR 43052, Oct. 26, 1984; 51 FR 4165, Feb. 3, 1986; 52 FR 11989, Apr. 14, 1987; 53 FR 27851, July 25, 1988]

§ 520.315 Cefadroxil powder for oral suspension.

(a) *Specifications.* Cefadroxil powder is reconstituted to form a 50 milligram-per-milliliter aqueous suspension.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) For use in dogs as follows:

(i) *Indications for use.* For treating genitourinary tract infections (cystitis) caused by susceptible strains of *Escherichia coli*, *Proteus mirabilis*, and *Staphylococcus aureus*; and skin and

soft tissue infections including cellulitis, pyoderma, dermatitis, wound infections, and abscesses caused by susceptible strains of *Staphylococcus aureus*.

(ii) *Amount.* 10 milligrams per pound of body weight, twice daily.

(2) For use in cats as follows:

(i) *Indications for use.* For treating skin and soft tissue infections including abscesses, wound infections, cellulitis, and dermatitis caused by susceptible strains of *Pasteurella multocida*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Streptococcus* spp.

(ii) *Amount.* 10 milligrams per pound of body weight, once daily.

(3) *Limitations.* Discard unused portion of reconstituted product after 14 days. Treatment should continue for 48 hours after animal is afebrile or asymptomatic. If no response after 3 days, discontinue treatment and reevaluate therapy. Not for use in animals raised for food production. Safe use in pregnant or breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[53 FR 27344, July 20, 1988]

§ 520.390 Chloramphenicol oral dosage forms.

§ 520.390a Chloramphenicol tablets.

(a)(1) *Specifications.* Each tablet contains 100, 250, or 500 milligrams, 1 or 2.5 grams of chloramphenicol.

(2) *Sponsor.* In § 510.600(c) of this chapter: No. 000010 for 100-, 250-, and 500-milligram and 1-gram tablets; No. 000856 for 100-, 250-, and 500-milligram tablets; No. 017030 for 100-milligram tablets; No. 000010 for 100-, 250-, and 500-milligram and 1- and 2.5-gram tablets; No. 000069 for 250-milligram tablets.

(3) *Conditions of use.* *Dogs*—(i) *Amount.* 25 milligrams per pound of body weight every 6 hours.

(ii) *Indications for use.* Oral treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.

(iii) *Limitations.* Laboratory tests should be conducted, including in vitro culturing and susceptibility tests on